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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,349	05/15/2001	Daniel Plaksin	87534-2800	2778

28765 7590 06/04/2003

WINSTON & STRAWN  
PATENT DEPARTMENT  
1400 L STREET, N.W.  
WASHINGTON, DC 20005-3502

EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 06/04/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/858,349

Applicant(s)

PLAKSIN, DANIEL

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 11-18, 20, 37-39 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 10, 19, 34-36 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-12 and 19; the peptide species FPTGDLAEK; antigen, TNF in Paper No. 9 is acknowledged. The traversal is on the ground(s) that Group II should be examined with Group I. Applicants state that the claims of Group I recite all the features, which are also recited in claims of Group II. This is not found persuasive because the claims of Group II are derived from the randomized sequence of CDR3. Group I may not include this randomized CDR3 sequence. Rather, only a single chain polypeptide sequence.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-8, 11-18, 20, 37-39 and 41-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

**(3) Status of Claims**

Claims 1-20 and 34-44 are pending in the application.

Claims 21-33 have been cancelled in the 5/15/03 Amendment.

Claims 34-44 have been added.

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Claims 5-8, 11-18, 20, 37-39 and 41-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as stated above.

Applicants state at page 6 of the REMARKS that the claims that read on the species are claims 1-3, 9-10, 13-16 and 18-20. However, the claims that read on the elected species are claims 1-4, 9-10, 19, 34-36 and 40.

Claims 1-4, 9-10, 19, 34-36 and 40 are under examination as being drawn to the elected invention and reads on the elected species.

#### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The peptide

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sequence with Lys at position 44, Leu at position 45 and Trp at position 47 is stated at page 5, lines 22-24 as critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The specification recites that the K LW is a crucial scaffold element representing VH/VL interface in the exemplary library. However, the elected claim (10) species FPTGDLAEK does not contain the said crucial elements or residues.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 9-10, 19, 34-36 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is confusing as to the characterization of the claimed compounds in the absence of any structural formula that normally identifies or characterizes a polypeptide compound. It is not clear as to the maximum limit included

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by the term "at least one charge". The specification does not recite for more than one charge in the region considered critical.

B. Claims 3 and 35 are confusing and broaden the base claim 1 with the recitation of different and various compounds such as polynucleotide, vectors, phage display library and etc. The term "unique", within the claimed context, is indefinite as to the scope of said term. Furthermore, claim 1 does not recite for a randomized CDR3.

C. Claims 4 and 36 are indefinite as they relate to a method step and broaden the base claim with the recited E. coli.

D. Claims 10 and 40 are confusing as to the recited 95 and 100C. Also, there is no Seq. ID. No. assigned for the sequence.

E. In claim 34, the term "substantially" is a relative term. The basis of said term is not defined in the specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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Claims 1-4, 9-10, 19, 34-36 and 40 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The claimed polypeptide comprising a single domain of the variable region of the heavy chain of an antibody molecule which is soluble and stable and capable of binding a specific antigen of interest wherein said polypeptide comprises a natural framework scaffold of a mammalian monoclonal antibody without induced mutations or modifications in the original VH/VL interface framework residues and the VH/VL interface comprises at least one charged residue is fully met by the polypeptide of Reiter et al (JMB, 1999). Note further the specification at page 26, line 17 which recites "... to clearly demonstrate that the VH protein is a predominantly monomer ~~we~~ performed analytical ultracentrifugation....."

Therefore, applicant appears not to be the sole inventor of the claimed invention, as evident from the published Reiter article and specification. Also, applicant cannot be entitled to the foreign priority based on an application filed in Israel on 11/11/1998. Applicant has not filed a certified copy of the Israel application as required by 35 U.S.C. 119(b).

No claim is allowed.

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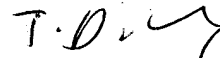
**REASSIGNMENT OF EXAMINER**

The examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1639 to the examiner below.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
June 2, 2003